Testimony
Before the Committee on Homeland Security
Subcommittee on Prevention of Nuclear and Biological Attack
United States House of Representatives

Implementing a National Biodefense Strategy

Statement of
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For Release on Delivery
Expected at 2:00pm
Thursday, July 28, 2005

Good afternoon, Chairman Linder and Subcommittee members. I am Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). I appreciate the opportunity to share with you CDC's unique role and contributions to building national biodefense capacities, particularly with regard to *Biodefense for the 21st Century*.

The philosophy of public health during the 20th century has been to prevent natural outbreaks. In the 21st Century, however this is not enough. The threat of terrorism necessitates that we improve our public health and medical systems so that we can respond with greater flexibility, speed, and capacity to handle mass casualties and large-scale emergency response in coordination with our traditional emergency response partners as well as those at Department of Homeland Security (DHS) and Department of Defense (DoD).

HHS is responsible for leading Federal public health efforts to ensure an integrated and focused national effort to anticipate and respond to emerging biological and other weapons threats. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the state and local medical and public health response to mass casualty events. Within HHS, CDC supports these activities through extensive coordination and collaboration with a number of federal departments and agencies.

CDC'S Strategic Preparedness Framework

The events of September and October 2001 made it very clear that terrorism is a serious threat to our Nation and the world. The Bush Administration and Congress responded forcefully to this threat by providing funding to strengthen our medical and public health capacities to protect our citizens from future attacks. To support HHS, CDC has made terrorism preparedness and emergency response one of two overarching agency goals and has built an infrastructure to catalyze and implement biodefense activities and collaborate with our Federal, state, and local government partners as well as with the private sector, non-governmental organizations, and tribal nations.

To do this effectively, CDC has established nine agency preparedness goals to strategically focus and efficiently direct CDC resources. For the purposes of this testimony each of the goals has been categorized according to the four essential components of our national biodefense program as identified in the HSPD-10.

1. Threat Awareness:
   - Decrease the time needed to classify health events as terrorism or naturally occurring in partnership with other agencies.
2. Prevention and Protection:
   - Increase the use and development of interventions known to prevent human illness from chemical, biological, radiological agents, and naturally occurring health threats.

3. Surveillance and Detection:
    - Decrease the time needed to detect and report chemical, biological, radiological agents in tissue, food or environmental samples that cause threats to the public's health.
    - Improve the timeliness and accuracy of information regarding threats to the public's health as reported by clinicians and through electronic early event detection, in real time, to those who need to know.
4. Response and Recovery:
    - Decrease the time to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health.
    - Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.
    - Decrease the time needed to restore health services and environmental safety to pre-event levels.
    - Increase the long-term follow-up provided to those affected by threats to the public's health.

In addition to these eight goals, CDC has a ninth goal under the heading of "Improvement" to decrease the time needed to implement recommendations from after action reports following threats to the public's health. Taken together these goals provide CDC a strategic framework from which to establish and implement preparedness programs with the goal of integrating our activities with those of our emergency response partners at all levels of government and the private sector.

Key Activities and Accomplishments

For the purposes of this testimony, I will now share with you CDC's unique blending of leadership and supporting roles under *Biodefense for the 21st Century* highlighting three priority areas:

- Laboratory Capacity
- Surveillance and Detection
- Response Capacity

For each of these areas, I will address CDC's activities and accomplishments toward building these capacities at the local, State and Federal levels.

LABORATORY CAPACITY

CDC is internationally recognized as a world leader for its premier clinical and chemical laboratories. To help strengthen our nation's laboratory capacity in responding to potential terrorism threats, we are aggressively moving forward on several fronts.

Laboratory Response Network Activities

The Laboratory Response Network (LRN) is a unified network of domestic and international laboratories that seeks to meet the needs for analysis of all

specimen/sample types (e.g., clinical, environmental, food) and agent types (e.g., chemical, biological, radiological). The objective of the LRN is to ensure an effective laboratory response to bioterrorism by helping to improve the Nation's public health laboratory infrastructure, through uniform diagnostic standards and protocols. Currently, there are more than 150 laboratories, representing all 50 states which make up the LRN. In addition more than 10 Federal agencies or departments actively participate in supporting the LRN including CDC, Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Department of Energy (DOE), Environmental Protection Agency (EPA), DoD, Federal Bureau of Investigation (FBI), and DHS.

To further expand and improve national laboratory response to an event, the Interagency Consortium of Laboratory Networks (ICLN) is a network of networks which was established six months ago to promote collaboration, communication, and technical acuity throughout the government's overall response strategy. This DHS-led group includes representatives from HHS (including CDC), USDA, DoD, DOE, EPA, Department of Commerce, Department of the Interior, Department of Justice, and the State Department. Together, all of these lab networks cover the diverse biological, chemical, radiological and nuclear materials that may be detected in clinical, environmental or food samples. The ICLN envisions a US homeland security infrastructure with a coordinated and operational system of laboratory networks that provides timely, high quality, and interpretable results for early detection and effective consequence management to acts of terrorism and other events requiring an integrated laboratory response.

National Interagency Biodefense Campus Initiative

The National Interagency Biodefense Campus (NIBC) is standing up at Fort Detrick to leverage and expand key competencies to achieve productive and efficient interagency cooperation in support of Homeland Security Biodefense. The co-location and collaboration of partners from DoD, HHS, DHS, and USDA provides a unique opportunity for coordinating and synchronizing areas of common interest among the federal agencies involved in medical research and/or biotechnology related to biodefense. The confederation of members promotes federal interagency coordination in facilities planning, technology sharing, and sharing of expertise, while minimizing duplication of effort, technology, and facilities.

CDC's Environmental Health Laboratory

CDC and the Agecy for Toxic Substances and Disease Registry (ATSDR) is responsible for detecting, responding to, and preventing human illness caused by a chemical release. Highlights of our accomplishments include:

- Developing a Rapid Toxic Screen to analyze human blood and urine samples for 150 chemical agents likely to be used in chemical terrorism.

- Assisting local, state, and federal agencies during national and international chemical terrorism events, providing chemical and toxicologic expertise, etiologic chemical analysis, and clinical guidance.
- Helping to increase state and local chemical lab capacity through funding, technical assistance, training and the conduct of drills and exercises.
- Supporting surveillance for chemical terrorism events through the American Association of Poison Control Centers' Toxic Exposure Surveillance System (TESS), which monitors and analyzes real-time data from the nation's poison-control centers.

Select Agent & Toxins Program

Through the Select Agent and Toxins Program within CDC, HHS regulates the possession, use, and transfer of 39 biological agents and toxins that have the potential to pose a severe threat to public health and safety. The CDC Select Agent and Toxins Program oversees these activities and registers all laboratories and other entities in the United States that possess, use, or transfer a select agent or toxin.

Currently there are 333 entities registered with the Select Agent and Toxins Program including academic institutions; biomedical centers; commercial manufacturing (e.g., the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories (including clinical and diagnostic laboratories); and research facilities.

Similarly, USDA has the responsibility of regulating pathogens that affect animals or animal products, plants or plant products. CDC collaborates with USDA to ensure that both regulations are harmonized and consistent.

SURVEILLANCE AND DETECTION

Historically, CDC has engaged in environmental and biological surveillance to track and respond to natural or unintentional man-made threats to the public's health. Because of this tradition, CDC has well-established partnerships with state, local and Federal agencies involved in bio-surveillance. These partnerships are being significantly expanded in the area of active reporting as well as exploring new methods of biologic threat detection domestically and globally.

BioWatch Preparedness and Response

A new system of providing around the clock detection capability is the BioWatch environmental surveillance program. This program utilizes automatic biohazard detection sensors placed strategically across the nation to detect potential threats to the public's health. CDC is working in tandem with the DHS, DOJ, and the EPA in the implementation of this program. These agencies have jointly developed draft guidance for BioWatch Preparedness and Response. This guidance is a three part tool that clearly articulates protocols and procedures for BioWatch-specific environmental sampling and response.

BioSense

BioSense is a significant expansion of information that CDC has traditionally collected from Federal, state and local reporting sources. It is a comprehensive public health data mining activity that integrates traditional and novel sources of public health data to enhance detection, quantification, and localization of possible bioterrorism attacks and outbreaks. In addition, it directly supports epidemiological investigation, event containment, and emergency response and recovery operations.

- BioSense also provides Early Event Detection (EED) and Situational Awareness (SA) capabilities to state and local public health departments, and specifically to cities where BioWatch sensors have been deployed. There are approximately 400 users enrolled representing 49 states, one territory, and 34 major metropolitan areas. Current data sources include DoD and Veterans Affairs (VA) ambulatory care data, laboratory test orders from Lab Corp Corporation, and BioWatch sensor results.

- BioSense continues to refine and expand this important data resource and is currently collaborating with the EPA on the potential use of water system testing data as another source for Early Event Detection as well as with DoD and the VA in strengthening their detection capacity through the utilization of BioSense data.

Biological Threat Characterization Program

CDC is an active participant in the Biological Threat Characterization Program (BTCP) which is a component center of the National Biodefense Analysis and Countermeasures Centers (NBACC) within DHS. A number of Federal agencies participate in this program including the FBI, CIA and DoD. BTCP has been tasked to provide bi-annual risk assessments for biological threat agents of concern. CDC subject matter experts are providing technical input to this process and will participate in the review of the final results.

Global Disease Detection

CDC is renowned as an international public health agency. Medical doctors, researchers, and epidemiologists from around the world contact CDC for advice on the evaluation and diagnosis of patients feared to have bioterrorism-associated or emerging infectious diseases. CDC staff are available twenty four hours a day, seven days a week to provide telephone and on-line consultations.

The Global Disease Detection initiative aims to recognize infectious disease outbreaks faster, to improve the ability to control and prevent outbreaks, and to detect emerging microbial threats. CDC will continue implementing a comprehensive system of surveillance by expanding the Emerging Infections Program and the Field Epidemiology and Laboratory Training Program. This network is a phased approach that requires ongoing support for existing country/regional platforms while bringing a high level of focus and attention to develop new sites. An effective network will have a strategic presence across the globe with an information technology and laboratory infrastructure

that would allow for the broadest possible detection and response capacities before a significant event occurs. Additional activities include improving early warning systems; researching new viral strains; aiding in collaborations with multinational organizations; and augmenting surveillance.

Recently CDC experts have assisted in ruling-out smallpox in a patient in Africa, and in providing injury checklists to help evaluate victims of the London terrorist bomb attacks.

CDC also has provided direct, in-country technical and operational support to large-scale international activities, such as the 2004 Summer Olympics in Athens, Greece.

RESPONSE CAPACITY

CDC is unique in its ability to rapidly mobilize pharmaceuticals and medical supplies to anywhere in the country within a 12 hour window from the decision to deploy these assets. In addition, our agency can bring to bear its formidable arsenal of scientific knowledge and subject matter expertise to assist in responding to and containing public health emergencies. Our goal is to increase this capacity even more with a priority focus on building response capacity at the state and local levels.

Preparedness and health security are a shared Federal, state and local responsibility. NIH is leading the way in the development of new medical countermeasures to threats we face. HHS has completed contract awards for the acquisition by the Strategic National Stockpile (SNS) of several new countermeasures, including the next-generation anthrax vaccine, under Project BioShield. CDC, meanwhile, is working closely with state and local health departments, federal agencies and departments including FDA, HRSA, DoD and other key stakeholders to create a seamless response network to ensure that these countermeasures can be delivered in a timely and effective fashion.

We have accomplished much but there is much more to be done. We continually explore options to strengthen the dispensing of countermeasures to save as many lives as possible in those first critical hours or days of a major emergency. HHS is working in concert with partners and stakeholders to advance the best strategies to ensure medical countermeasures are readily available to protect individuals in the event of a terrorist attack or naturally occurring health problem.

Cities Readiness Initiative

CRI is a multi-agency initiative spearheaded by HHS and DHS. Other participating agencies include DOJ, FBI, VA and the United States Postal Service. The intent of the Cities Readiness Initiative (CRI) pilot is to build capacity for catastrophic public health emergency response in densely populated areas. Specifically, the Cities Readiness

Initiative is designed to significantly improve the operational capability of 21 large metropolitan areas to receive, distribute and dispense SNS assets. Each designated city should be able, in the wake of a bioterrorism event for which antibiotics are an appropriate countermeasure, to provide such prophylaxis to the known and potentially affected population within 48 hours of the time of the decision to do so.

Under this program, 20 cities and the District of Columbia receive direct assistance through CDC's Public Health Emergency Preparedness cooperative agreement. Participating cities include: Atlanta, Boston, Chicago, Cleveland, Dallas, Denver, Detroit, Houston, Las Vegas, Los Angeles, Miami, Minneapolis, New York City, Philadelphia, Phoenix, Pittsburgh, St. Louis, San Diego, San Francisco, Seattle, and the District of Columbia/National Capitol Region.

CDC's Division of Strategic National Stockpile (DSNS) supports this initiative with on-going technical assistance to ensure SNS assets are received and dispensed efficiently and effectively.

CDC conducted its own internal assessments in all 21 cities at baseline. These preliminary assessments showed initial improvement. CDC is currently working with partners and a research organization to externally validate CDC's rating tool.

State and Local Readiness Program

CDC administers the Public Health Emergency Preparedness cooperative agreement to assist State and local public health programs in building and improving their preparedness capacities. This includes overseeing their progress in completing activities that help address CDC's nine preparedness goals mentioned earlier in this testimony, by monitoring 34 measures that have been identified as good indicators of public health emergency preparedness. As we learn more about effective methods of emergency preparedness, the development and refinement of these measures will be conducted in collaboration with state, local, territorial, and tribal public health input as well as with key partners including National Association of County and City Health Officials (NACCHO), Association of State and Territorial Health Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), Association of Public Health Laboratories (APHL), DHS, and the Federal Emergency Management Agency. Note that these measures were initially refined through review of the *Target Capabilities List* from DHS which provides defines "nationally accepted preparedness levels of first responder capabilities" for state and local programs.

Risk Communication

HHS coordinates the development of Department-level training opportunities related to public health and medical emergency response, including providing training opportunities for its employees (civil service and uniformed) with the basic tools necessary to manage and operate during a public health emergency.

CDC has developed a preparedness education strategy that targets public health agencies, healthcare organizations, clinicians and laboratorians needed to collaborate to detect, investigate, respond to, and recover from a public health emergency.

One component of CDC's preparedness education strategy is directed to developing and providing information to public health workers and clinicians in advance of an emerging threat. This education is developed to prepare and alert clinicians and public health workers in advance and "just in case" of a potential threat in their community, to recognize symptoms, syndromes, or patterns of illness that require reporting and to improve their capacity to respond.

In addition, CDC has invested in the development of "just-in-time" educational materials, which are educational methods to provide prompt, emergent information as needed and as it becomes available. During an emergency event, CDC is able to rapidly provide new information to clinicians and public health professionals, as rapidly as possible, through web-based and live satellite broadcast educational programs and other communication channels, to improve response efforts.

Conclusion

CDC is working hard to meet the public health challenges of the 21st century. We are redefining our mission, restructuring the way we conduct business, and reorienting our goals. We are changing as an agency because we must respond faster and more efficiently as we protect our nation's health in today's world.

To succeed we rely on many partners including the medical community, federal, state and local governments, innovators and the highly talented CDC workforce. CDC's new business model allows us to be the nimble organization that we need to be to combat world threats to the public's health.

Thank you for the opportunity to be here today. I would be happy to address any questions that you may have.